

### III. REMARKS

Claims 1, 3, 5-8, 10, 11, and 18-26 are pending in this application. Claims 18-25 were previously withdrawn from consideration. By this Amendment, claim 1 has been amended. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

Entry of this Amendment is proper under 37 CFR 1.116(b) because the Amendment: (a) places the application in condition for allowance as discussed below; (b) does not raise any new issues requiring further search and/or consideration; and (c) places the application in better form for appeal. Accordingly, Applicants respectfully request entry of this Amendment.

Applicants do not acquiesce in the correctness of the rejections and reserve the right to present specific arguments regarding any rejected claims not specifically addressed. Further, Applicants reserve the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

In the Final Office Action and its accompanying Notice to Comply, the Office alleges that the application fails to comply with 37 CFR 1.821 through 1.825. Specifically, the Office requires that a sequence listing including the nucleotide sequences found on pp.17-18 of the application be submitted in both paper copy and computer readable form (CRF). In response, submitted herewith is a sequence listing of the nucleotide sequences in both paper copy and CRF. Applicants assert that the paper and CRF copies of the sequence listing are the same and contain no new matter. Applicants request that the application be amended to include the sequence listing

submitted herewith.

In the Final Office Action, claims 1, 3, 5-8, and 11 are rejected under 35 USC 102(b) as allegedly being anticipated by US Patent No. 6,399,124 to Lesens et al. Specifically, the Office alleges that Lesens et al. teach the composition of claim 1, wherein the composition contains prebiotic fibers chosen from "...fructo-, genito-, galacto-, isomalto-, manno- or xylo oligosaccharides...The preferred galacto-oligosaccharides compris[ing] a saccharide part consisting of 2 to 5 repeating units and preferred fructooligosaccharides [being] inulin-oligofructoses...which may comprises, for example, 1-9 repeating units." Final Office Action at 4. In addition, the Office states that "[e]xamples 1, 4 and 5 specifically teach edible compositions, coatings and decorations containing galactooligosaccharide P7L, Raftilose L30 and Actilight 950P."

*Id.*

Applicants assert, however, that Lesens et al. fail to teach or suggest the use of both a galacto-oligosaccharide and a fructo-oligosaccharide in a single composition, such as the composition of claim 1. Accordingly, Lesens et al. fail to teach each and every element of the rejected claims.

As noted by Applicants, it has surprisingly been found that "the prebiotic properties of FOS are significantly improved by the presence of galacto-oligosaccharides (GOS) and that the effects of FOS and GOS are more than additive, i.e. a synergistic effect in promoting the growth of beneficial bacteria, such as bifidobacteria and lactobacilli, has been observed." Application at 3. All of the relevant compositions taught by Lesens et al. include *either* a fructo-oligosaccharide (example 1, tables 2 and 4; example 4, table 7) *or* a galacto-oligosaccharide (example 1, table 3; example 5). Thus, Applicants

assert, Lesens et al. do not teach a composition comprising both a fructo-oligosaccharide and a galacto-oligosaccharide, as recited in claim 1, and do not, therefore, anticipate any of the rejected claims.

In fact, Lesens et al. appear not to have even contemplated such a combination. The approach of Lesens et al. in improving prebiotic activity is limited to increasing the quantity of prebiotic fibers in the composition. “[I]t has been observed that the more solid concentrate of fibers the diet contains, the more the intestinal transit of these fibers is retarded, with a corresponding positive influence on the development of the lactic acid bacteria in the intestine.” Column 5, lines 38-42. Lesens et al. themselves note the drawback of such an approach. “[T]he dessert may be designed so as to be able to potentially provide up to a maximum of 10 g of fibre per dessert, higher quantities of fibers indeed inducing an unpleasant feeling of heaviness in the stomach.” Column 5, lines 23-26.

The claimed combination of FOS and GOS in a single composition, with its unexpected synergistic effect, avoids the limitations identified by Lesens et al. “As a result of this synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved *in vivo* while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually.” Application at 3.

Applicants assert, therefore, that the rejected claims are neither anticipated by nor obvious over the teachings of Lesens et al. Nevertheless, in order to make the distinctions above more clear, claim 1 has been amended to include a recitation that the

prebiotic property of the FOS and GOS is synergistic. Accordingly, for the reasons given above, Applicants assert that the rejected claims are not anticipated by Lesens et al. and respectfully request withdrawal of the rejection.

In the Final Office Action, claims 1, 5, and 10 are rejected under 35 USC 103(a) as allegedly being unpatentable over Lesens et al. Specifically, the Office alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Lesens et al. to make a composition of FOS, GOS, proteins, carbohydrates, and fats.

For the reasons given above, Applicants respectfully assert that such a combination would not have been obvious to one of ordinary skill in the art. Lesens et al. make no mention of a synergistic effect of FOS and GOS, as recited in amended claim 1. Applicants assert, therefore, that the rejected claims are not obvious over Lesens et al. for the reasons given above and respectfully request withdrawal of the rejection.

In the Final Office Action, claims 1, 3, 5, 7, 8, 10, and 11 are rejected under 35 USC 103(a) as allegedly being unpatentable over Moro et al., Boehm et al., and Rigo et al. in view of Lesens et al. Specifically, the Office alleges that Moro et al., Boehm et al., and Rigo et al. each “disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein...,” Final Office Action at 7-8, and that these references and Lesens et al. teach the various amounts, ratios, and percentages claimed.

As argued in Applicants’ 31 July 2006 Amendment, Moro et al., Boehm et al., and Rigo et al. each describe infant formulas with amounts, ratios, and percentages of

oligosaccharides intended to approximate those of breast milk. “The mixture was combined to mimic the molecular size distribution of human milk oligosaccharides and to benefit from a possible synergistic effect of both compounds to stimulate the growth of *Bifidobacteria*.” Moro et al. at 292; “To investigate the effect of a preterm formula milk supplement consisting of oligosaccharides in similar proportions to human milk on the faecal flora and stool characteristics of preterm infants.” Boehm et al. at F178; “The aim of nutrition in newborn term infants during the first months of life, is to mimic growth, clinical status and biological parameters observed in healthy breast fed term infants.” Rigo et al. at 40. Thus, one skilled in the art would not be motivated to substitute the percentages of ingredients taught by Moro et al., Boehm et al., and Rigo et al. for those taught by Lesens et al. Moro et al., Boehm et al., and Rigo et al. specifically intend their compositions to mimic the contents of breast milk while Lesens et al. intend their composition to be used in a frozen dessert capable of promoting the growth of beneficial bacteria.

In addition, Applicants note that Lesens et al., Boehm et al., and Rigo et al. fail to even suggest a symbiotic effect of FOS and GOS on the growth of any species of beneficial bacteria. Moro et al., while noting the possibility of a synergistic effect of FOS and GOS, report results that do not support such an effect on *Lactobacilli*. “The number of *Lactobacilli* also increased significantly in both groups fed the supplemented formulas (versus placebo,  $P < 0.001$ ), but there was no statistically significant difference between the group fed formula with 0.4 g/dL oligosaccharides and the group fed formula with 0.8 g/dL oligosaccharides.” Moro et al., Abstract. The results of Boehm et al. support the lack of a synergistic effect. “*Lactobacilli* were also detectable in all infants at the study

entry. There was a significant increase in all groups during the course of the study period but there was no significant effect of the diet (data not shown). Neither was there a significant effect of the oligosaccharide supplement on the counts of *Bacteroides*, *Clostridium* species, *E. coli*, *Enterobacter*, *Citrobacter*, *Proteus*, *Klebsiella*, and *Candida*.” Boehm et al. at F179.

Thus, Applicants assert that amended claim 1, as well as each of claims 3, 5, 7, 8, 10, and 11, which depend therefrom, are not obvious in view of Moro et al., Boehm et al., Rigo et al. or Lesens et al., whether viewed individually or in any combination, since no combination of these references teaches a composition comprising FOS and GOS, which is capable of synergistically promoting the growth of *Lactobacilli*. Accordingly, Applicants respectfully request withdrawal of the rejection.

Applicants note that the Office has made no rejection of claim 26, added in Applicants’ 31 July 2006 Amendment. Accordingly, Applicants presume that claim 26 is allowed.

Also, Applicants note that the Final Office Action states, in response to Applicants’ 31 July 2006 Amendment, that Applicants’ arguments with respect to claims 8-12 have been considered but are moot in view of the new grounds of rejection necessitated by Applicants’ amendments. Applicants note that by Applicants’ 31 July 2006 Amendment, claims 1, 3, 5-8, 10, 11, and 18-26 were pending, claims 18-25 having been withdrawn from consideration. Appropriate clarification of which of Applicants’ arguments were considered by the Office before issuing the Final Office Action is respectfully requested.

In view of the foregoing, Applicants respectfully request withdrawal of the rejections and allowance of the application. Should the Examiner require anything further from Applicants, the Examiner is invited to contact Applicants' undersigned representative at the number listed below.

Respectfully submitted,



Stephen F. Swinton, Jr.  
Reg. No. 53,661  
for  
Gary M. Lobel  
Reg. No. 51,155

Date: 10 August 2007

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
973-593-7553